NDA 21-083/S-004 AUG 25 2000

Wyeth-Ayerst Research
Attention: Randall Brenner
Manager, Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Mr. Brenner:

Please refer to your supplemental new drug application dated August 16,2000, received August 17,2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rapamune® (sirolimus) Oral Solution, lmgImL.

We acknowledge receipt of your submission dated August 22,2000.

This supplemental new drug application provides for:

> Addition of information regarding Rapamune® (sirolimus) Tablets, 1 mg to the package insert.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (text for the package insert submitted August 22,2000).

Please submit 20 copies of the FPL as soon as they are available, in no case more than 30 days after they are printed. Please individually mount ten of the copies on heavyweight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format — NDAs (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplemental NDA 21-083/S-004." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MID 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Matthew A. Bacho, Regulatory Project Manager, at (301) 827-2127.

Sincerely,

Renata Albrecht, M.D.
Acting Director
Division of Special Pathogen and
Immunologic Drug Products
Office of Evaluation IV
Center for Drug Evaluation and Research